DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#8

MAY 8 1990

Re: Synarel
Docket No. 90E-0156

Charles E. Van Horn, Esq.
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,234,571 filed by Syntex (U.S.A.) Inc. under 35 U.S.C. 156. The human drug product claimed by the patent is Synarel (nafarelin acetate), New Drug Application (NDA) 19-886.

A review of the Food and Drug Administration's official records confirms that Synarel was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that NDA 19-886 represents the first permitted commercial marketing or use of the active ingredient, nafarelin acetate. The NDA was approved on February 13, 1990 which makes the submission of the patent term extension application on April 10, 1990 timely within 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)

cc: Tom M. Moran, Esq.
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